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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/643,674
Filing Date: August 19, 2003
Appellant(s): HYON ET AL.

David L. Suter
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10-28-2009 appealing from the Office action mailed 10-28-2008.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

U.S. Application Serial No. 11/643,673.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,030,402	ZACHARIADES	07-1991
3,886,056	KITAMARU et al	05-1975
5,037,928	LI et al	08-1991

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Rejection under 35 U.S.C. 251

Claims 40, 41, 43, 45-53, 84, 85, 87, 89-97 and 99-101 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to claim subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope of claim subject matter surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

The following subject matter appears to be an attempt to recapture subject matter surrendered during prosecution of the parent application:

The amendments cited below were made in parent application Serial No. 08/640,738, which issued as Patent 6,168,626.

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In Amendment B filed 04-02-1997, the phrase “molded articles” was amended to set forth **“molded articles having orientation of crystal planes”** in order to distinguish over Rosenzweig, US 5,030,487. The phrase “molded articles having orientation of crystal planes” was further amended to read **“molded articles having orientation of crystal planes in a direction parallel to a compression plane, wherein the molded article is crosslinked slightly”** in Amendment C filed 12/5/1997 in order to distinguish over cited Patent 4,655,769 to Zachariades.

The current recitation “block” in claims 40 and 84 is a broadening of the recitation of a “molded block” set forth in the original claims. The phrase “molded article” was changed to read **“molded block”** in Amendment F filed 02-25-1999 in order to distinguish over Patent 3,886,056 to Kitamaru et al. The current term “block” is broader in scope than the phrase “molded block” and broader in scope than the recitation **“molded block having been crosslinked slightly ... so as to have orientation of crystal planes in a direction parallel to the compression plane”** as set forth in claim 1 after Amendment F in Application No 10/640,738..

The instant claims are broadened by failing to recite that the molded article is made by compression deforming the heated article **“by compressing the block in a direction perpendicular to a compression plane so as to deform the block”**. This limitation was added in Amendment D filed 09-03-1998 in order to resolve the rejection under 35 US 112, second paragraph, that the phrase “orientation of crystal planes in a direction parallel to a compression plane” discussed above was indefinite when the orientation of the compression plane is not defined. This limitation is not present in claims 40, 41, 43, 45, 52-53, 84, 85, 87, 89, 96, 97 and 99-101.

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The instant claims do not recite the limitation “**said block after cooling having a thickness range of 5 to 10 mm in a direction perpendicular to the compression plane**”.

Amendment G filed 09-10-1999 introduced this limitation to distinguish the “molded block” recitation from the films and sheets disclosed by Kitamura et al.

Amendment G filed 09-10-1999 also introduced the limitation “**under pressure**” to the phrase “keeping the block in a deformed state under pressure” in order to distinguish over the process taught by Kitamura et al.

Claim Rejections - 35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 40, 41, 43, 45-53, 84, 85, 87, 89-97 and 100-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zachariades (5,030,402) in view of Kitamaru et al (3,866,056).

Zachariades teaches compression deformation of oriented UHMWPE to obtain enhanced properties. Compression molding at between 80⁰C and the melting temperature of the polymer, preferably between 100⁰C and 130⁰C, and shaping into a final product is taught in column 3, lines 25-44. Zachariades also teaches maintaining pressure after cooling to ambient temperature to aid in retaining the attained chain orientation (column 4, lines 1-11). Zachariades further teaches that the molded UHMWPE can be thermally annealed after removal from the mold (column 6, lines 50-54). Zachariades discloses radiation crosslinking as a post-processing step

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(column 4, lines 11-18). Deformation of the UHMWPE perform to an acetabular liner is shown in Figures 4 and 5. The difference from the instantly claimed method is that Zachariades does not mention crosslinking UHMWPE by irradiation before compression deformation.

Kitamaru et al disclose a process for irradiating polyethylene, including polyethylene preferably having a molecular weight from 2×10^5 to 1×10^6 and polyethylene having a molecular weight of 4×10^6 , with ionizing radiation to produce crosslinked polyethylene having a gel content of at least one weight percent (column 1, line 65, to column 2, line 50). Irradiation of polyethylene with dosages from 0.2 to 16 Mrads is taught in column 3, lines 1-10. A process comprising heating to produce a molten state, extending the polyethylene under increased pressure, and cooling the article while the extended dimension is maintained is taught in column 3, lines 13- 45. Irradiation followed by compression at 180°C followed by cooling and orientation of crystal planes in a direction parallel to the compression plane is disclosed in Examples 1-3.

It would have been obvious to one skilled in the art at the time of the invention to irradiate UHMWPE, as taught by Kitamaru et al in an analogous method, to provide a slightly crosslinked irradiated UHMWPE perform as the starting UHMWPE to be used in the compression molding method steps for orienting and extending UHMWPE taught by Zachariades. Zachariades teaches that those skilled in the art to which the disclosed invention relates would recognize changes and different embodiments possible without departing from the spirit and scope of the invention. Zachariades provides further motivation by teaching that the UHMWPE can be radiation crosslinked after molding under pressure. Kitamaru et al provide motivation to employ irradiated UHMWPE by teaching that irradiation crosslinked UHMWPE

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can be deformed under pressure and will provide a high melting temperature and softening temperature polyethylene with improved transparency and excellent dimensional stability at high temperatures (column 1, lines 5-9, and column 2, lines 13-25). One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of obtaining both enhanced mechanical properties resulting from the disclosed compression deformation method taught by Zachariades and enhanced properties resulting from irradiation crosslinking before deformation of the crosslinked UHMWPE taught by Kitamaru et al. With respect to claims 49 and 50, It would have been obvious to one skilled in the art at the time of the invention to determine the thickness of UHMWPE product desired for a particular application and to prepare the block according to the combination of the teachings of Kitamaru et al and Zachariades as set forth above. Kitamaru et al do not teach any thickness limitations. Zachariades teaches treating polyethylene having thickness greater than the thickness set forth in the instant claims in the examples.

Claim 99 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zachariades (5,030,402) in view of Kitamaru et al (3866,056), as applied to claims 40, 41, 43, 45-53, 84, 85, 87, 89-97 and 100-101 above, and further in view of Li et al (5,037,928). Neither Zachariades nor Kitamaru et al teaches cutting a block of UHMWPE to obtain a component for implant. Li et al disclose a process for manufacturing UHMWLPE shaped articles comprising heating and cooling in an inert gas atmosphere. Li et al teach heating UHMWLPE under pressure followed by cooling under pressure and cooling while releasing the pressure without allowing remelting, including forming an UHMWLPE article either before heating or after heating and cooling

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(column 2, line 43, to column 3, line 20 and column 5, lines 1-5). Li et al also teach that the disclosed process is particularly useful for manufacturing shaped articles from materials having cross-sectional dimensions of at least 1 inch by 1 inch and having temperature gradient problems during the cooling step and for producing articles at least 0.2 inch in thickness (column 3, lines 46-58). Example 5 discloses cutting and machining the treated UHMWPE bar.

(10) Response to Argument

Rejection under 35 U.S.C. 251:

(I) Appellant argues that the current claims reflect prosecution of a patentably distinct invention that embodies limitations that are more narrow in significant aspects than the claims of US 6,168,626. Therefor, the error upon which the reissue application is based is an error that can be corrected by reissue. The error upon which the reissue application is based is that appellant did not claim preferred levels of irradiation, i.e. “at least about 1 MR”. Claims 3-6 are the only method claims in US 6,168,626. Claim 3 in US 6,168,626 does not limit the irradiation dose. Claim 4 in US 6,168,626 sets forth irradiation in the range of 0.01 to 5.0 MR. Thus the instant claims are narrower in comparison to claim 3 but broader in comparison to claim 4 of US ‘626 with respect to irradiation dose. The instantly recited limitation “at least about 1 MR” is not considered to be a significant aspect with respect to patentability of the instant claims since the limitation is encompassed by the recitations in the patented claims.

Appellant further argues that the present claims are directed to a different invention than prosecuted in the issued parent, US 6,168,626. Appellant further argues that applicant’s remarks and amendments in pursuit of the original claims are not relevant to the scope of the instant

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claims because the instant claims were restricted from claims 1-11 in US 6,168,626 as being drawn to a distinct and independent invention. The instant claims were restricted from claims 1-11 of US 6,168,626 because claims 1, 2 and 7 are drawn to an UHMWPE molded block defined by the process for production, claims 3-6 are drawn to the process for production of the UHMWPE molded block and claims 8-11 are drawn to an artificial joint comprising the molded block. Issued claims 3-6 in US 6,168,626 are drawn to a method closely corresponding to the method set forth in the instant claims under appeal. The broadened aspects in combination with the narrower aspects of the instant method claims would be expected to result in products having different properties as a result of the claim limitations. However, the amendments made in pursuit of the original claims are considered to be relevant to the scope of the instant claims because the claims 3-6 method steps prosecuted in the parent application are significantly the same as the method steps set forth in the instant claims. Specifically, the original claims of the parent application recite irradiating the block, heating the crosslinked block to a compression deformable temperature, compressing and cooling the block. Specifically, the instant claims recite irradiating the block with at least 1 MR radiation level, heating the crosslinked block to a compression deformable temperature below the melting point of the UHMWPE, subjecting the heated block to pressure and cooling the block. Thus, the steps of irradiation and heating were considered in the prosecution of the original patented claims 3-6. It is noted that claim 4 of US '6262 recites a dose of irradiation from 0.01 MR to 5.0 MR and claim 5 recites a compression deformable temperature in a range of 50⁰C lower than the melting temperature of the crosslinked UHMWPE.

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(II) Appellant argues that the claims are not barred by the recapture rule because the broadening aspects of the reissue claims were never presented during prosecution of the '626 Patent and do not relate to subject matter surrendered during prosecution of US Patent 6,168,626. Appellant argues that the instant claim language is not of significantly broader scope because the terms inherently include the specifics set forth in the claims of US '626. See the Appeal Brief, pages 10-11. Appellant agrees that the instant claims present elements broader than elements present in the claims of the '626 Patent, i.e. patented claims 3-6, but argues that the claim recitations do not represent impermissible recapture of subject matter because the instant claims are directed to a distinct invention comprising a significant broadening never presented during prosecution of US '626". This argument is not persuasive because the instant claims under Appeal are different in scope from the claims presented in the initial reissue application 10/141,374 and restricted from the original patented claims 1-11 of US '626. Thus the significant differences between the issued claims of Patent '626 and the initial reissue claims are not found in the present reissues claims.

(III) Appellant argues that, if the present claims are viewed as related to the same invention as those issued in US 6,168,626, they are materially narrowed in other aspects so as to avoid recapture. Applicant argues that the present amendments narrowing the recited heating to "heating said crosslinked block up to a compression deformable temperature below the melting point of the UHMWPE" avoids the recapture bar because this aspect is significant from a technical and a patentability perspective.

This argument is unpersuasive because the limitation "below the melting point of the UHMWPE" while narrower than recited in the patented claims is encompassed by the patented

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claims and was, thus prosecuted in the original application that issued as US '626. See patented claim 5. In other words, claim 5, which was prosecuted and patented in US '626, includes the instantly recited method wherein the compression-deformation temperature is a temperature below the melting point of the crosslinked UHMWPE. While the focus on compression of crosslinked UHMWPE at a temperature below the melting point required in the instant claims is significantly more narrow than the recitation of temperatures ranging from below to above the melting point of the crosslinked UHMWPE in the issued patent claims, the narrowed focus is not considered to be sufficient to allow for broadening of other significant aspects of the patented method claims. Since claim 5 has been prosecuted and patented, the broadening aspects of the instant claims constitute recapture of surrendered material with respect to the recited method. The limitation with respect to subjecting crosslinked UHMWPE to pressure at a temperature below the melting point required in the instant claims is considered to be a significant narrowing only if the additional limitations of the patented claims are retained rather than broadened. Appellant has not pointed out any evidence that the instant claim limitation to temperatures below the melting point of the crosslinked UHMWPE is relevant to a rejection made during the prosecution of the issued patent, US '626.

With respect to the decision in *Ball*, “broader aspects of reissue claims do not deprive then of their fundamental narrowness of scope relative to the cancelled claims”, the facts of the case specifically the narrowing to recite a cavity element filled with a dielectric material is an added limitation that differs from the instant narrowing that selects a narrower recitation of an existing limitation in the issued claims.

With respect to the decision in *In re Clement*, “If the reissue claim is as broad as or broader in an aspect germane to a prior art rejection, but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim...”, appellant argues that the narrowing aspect of the instant claims is not “completely unrelated” to claim rejections made during prosecution of the ‘626 Patent. Appellant argues that if the narrower limitation in the reissue claims has been presented in the prosecution of US ‘626, the claims would have distinguished over the art applied during the prosecution of the ‘626 Patent.

Appellant argues that Rosenzweig does not teach compression deformation at a temperature lower than the melting point of UHMWPE. Thus the current limitation would have distinguished over Rosenzweig.

Appellant argues that Kitamaru et al disclosed heating UHMWPE above the melting point and applying pressure. Thus appellant argues that the current limitation would have distinguished over the reference.

Appellant argues that the rejection of claim 5 over Zachariades ‘769 was based on the reaching of thermal treatment at temperatures above the melting point of UHMWPE. However, Zachariades teaches thermal treatment at a “temperature close to or above the melting point of the polymer” so the instant limitation would not have distinguished over Zachariades ‘769.

The argument that the claim limitation narrowing the temperature employed for compression-deformation is “not completely unrelated” to the rejections made in the prosecution of US ‘626 is unpersuasive. While the limitation would have distinguished over some of the prior art references it is not related to any grounds of rejection made during the prosecution.

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This argument is unpersuasive because the instant narrower limitation “temperature below the melting point of the UHMWPE” was present in the broader limitation “temperature is in a range of 50⁰ C lower than a melting temperature of the crosslinked ultra high molecular weight polyethylene to 80⁰ C higher than the melting temperature” in claim 5 prosecuted in US ‘626.

In the instant case, reissue claims 40 and 84 are considered to be broadened in an aspect germane to surrendered subject matter in response to a prior art rejection in the prosecution of US 6,168,626 and narrowed in another aspect unrelated to the rejection of claims in the issued parent and thus barred by the recapture rule. Claims 40 and 84 are broadened by recitation of UHMWPE “block” rather than UHMWPE “molded block having orientation of crystal planes in a direction parallel to a compression plane”, by recitation of “subjecting said heated block to pressure” instead of “compressing the block in a direction perpendicular to a compression plane so as to deform the block”, and by omitting the requirement of a “thickness range of 5 to 10 mm in a direction perpendicular to the compression plane” after cooling.

Claims 40 and 84 are narrowed by the recitation “heating said crosslinked block up to a compression deformable temperature below the melting point of the UHMWPE”. Claim 5 of the issued Patent 6,168,626 recites “the compression-deformable temperature is in a range of 50⁰ C lower than a melting temperature of the crosslinked ultra high molecular weight polyethylene to 80⁰ C higher than the melting temperature”. Therefor the issues of heating to a temperature lower than the melting point was considered in the prosecution of US 6,168,626. The narrowing of the compression deformable temperature recitation is not considered to be directed to an amendment

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and/or argument made to overcome a prior art rejection in the original prosecution and thus there is recapture of surrendered material. See MPEP 1412.02 [R-5] C. The Third Step 2(a). Issued claim 3 merely recites “heating...to a compression-deformable temperature”. The issue of the claim limitation “heating...to a compression-deformable temperature’ compared with the claim limitation “heating to a compression-deformable temperature below the melting point’ is not related to the surrendered material in the prosecution of the original application.

Rejection of claim over Zachariades ‘402 and Kitamaru et al:

Appellant argues that there is no rationale for combining the teachings of the references other than impermissible hindsight.

Appellant argues that there is no reason other than impermissible hindsight to combine the teachings of Zachariades and Kitamaru et al. Appellant argues that the two references deal with fundamentally different material technologies.

This argument is unpersuasive. The disclosures of Zachariades and Kitamaru et al are analogous art in that both references disclose methods for treating ultra high molecular weight polyethylene. Zachariades discloses a method comprising compression-deformation in a solid state including orienting and extending a preform in more than one direction in a mold cavity, followed by cooling under compression for maintaining the orientation and extension attained. An objective is to provide enhanced and balanced planar mechanical properties and controlled dimensional stability. Zachariades Kitamaru et al disclose irradiating polyethylene to crosslink the polyethylene, followed by extending and orienting the polyethylene in at least one direction at a temperature at least an isotropic melting point of the crosslinked polyethylene, followed by

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cooling. The product is a high melting temperature polyethylene with excellent dimensional stability and high transparency. Kitamura et al teach both films and sheets. Acetabular cups, such as taught by Zachariades, are usually thin films or sheets. Example 1 discloses irradiation of polyethylene and compressing the gel sample followed by cooling to room temperature. In the rejection of record, Kitamaru et al is relied upon for teaching that irradiated polyethylene can be compression-deformed and cooled. Both references teach providing products comprising crosslinked, oriented and extended polyethylene.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Appellant argues that the references are combined in a fashion inconsistent with the process taught by the primary reference. Appellant bases this argument on the teaching of Zachariades to crosslink the UHMWPE after molding and argues that it would not have been obvious to crosslink the UHMWPE before molding, as set forth in the rejection as being suggested by the disclosure of Kitamaru et al.

Appellant argues that only certain features of the secondary reference are arbitrarily selected, specifically "crosslinking before extending" from the disclosure of Kitamaru et al. This argument is not persuasive This argument is not persuasive because, in the rejection of record,

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Kitamaru et al is relied upon for teaching that irradiated polyethylene can be compression-deformed and cooled. This is the only modification of the teaching of Zachariades required to arrive at the instantly claimed method.

Appellant argues that no rationale is provided for selecting the irradiation step taught by Kitamaru et al and not the application of pressure at a temperature above the melting point. Zachariades is relied upon for teaching heating at a temperature below the melting point in order to compression deform polyethylene in the solid state. Modification of this process step taught by Zachariades is not required to arrive at the instantly claimed method.

With respect to the claim 84 recitation “processing said cooled block to form said component (an artificial joint component), Zachariades teaches that the compression-deformed and cooled product is simultaneously shaped into the final product and that the UHMWPE can be used as a precursor for its machining into a final product (column 3, lines 43-44, and column 12, lines 21-26).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner’s answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Susan W. Berman/
Primary Examiner
Art Unit 1796
12/11/2009

Conferees:

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